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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/522,093

01/21/2005

Stefan Droschel

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EXAMINER

SCHIRO, RYAN RAYMOND

ART UNIT

PAPER NUMBER

4172

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/522,093	<b>Applicant(s)</b> DROSCHER ET AL.	
	<b>Examiner</b> RYAN SCHIRO	<b>Art Unit</b> 4172	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01/21/2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 8, 10-14, 16, 18 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9, 15 and 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/26/2007 and 01/21/2005</u> .                               | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election***

During a telephone conversation with Charles Gagnebin on 04/23/2008 a provisional election was made without traverse to prosecute the invention of group A. Furthermore, the species group A-II was elected. Affirmation of these elections must be made by applicant in replying to this Office action. Claims 11-14 and 19 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Claims 8, 10, 16 and 18 are non-elected species. Claims 1-7, 9 15 and 17 are presented for examination.

### **PCT:Lack of Unity**

#### ***Posteriori***

Lack of unity of invention may be may only become apparent “a posteriori,” that is, after taking the prior art into consideration, in the case of independent claims to a method of immobilizing a polymer hydrogel and a product consisting of an immobilized polymer hydrogel, unity of invention(i.e. species) is present a posteriori as A is common to both claims.

**Group A**, claims 1-10, and 15-18, drawn to a method of immobilizing a polymer hydrogel on the surface of a polymer substrate, class 427 subclass 547.

**Group B**, claims 11-14 and 19 drawn to a polymer substrate that has a polymer hydrogel immobilized on its surface, class 428 subclass 500.

The inventions listed as Groups A and B do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special

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technical features for the following reasons: the special technical feature which is referred to Annex B of Appendix A1 of the MPEP(Administrative Instructions under the PCT, "Unity of Invention"). The express "special technical features" is defined as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art."(Rule 13.2). Unity exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding claimed special technical features. In this case, the technical feature shared by each invention is a polymer substrate is used.

If applicant elects Group (A) invention, it is subject to further restriction as following because they are not so linked as to form a single general inventive concept under PCT Rule 13.1 as reasoned above.

**Group A-I**, claim(s) 8 and 16, drawn to a non-toxic photoinitiator consisting of riboflavin, morin, rutin or a mixture thereof.

**Group A-II**, claim(s) 9 and 17, drawn to a non-toxic photoinitiator consisting of nicotinic acid amide.

**Group A-III**, claim(s) 10 and 18, drawn to a non-toxic photoinitiator consisting of thioxanthone.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1 as discussed above.

Applicant is required, in reply to this action, to elect a single disclosed species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

With the election of the specific species, a generic concept will be identified by the examiner as the inventive group for examination.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Swan et al (US 2002/0004140 A1).

Claims are drawn to a method of immobilizing a polymer hydrogel on the surface of a polymer substrate, whereby a hydrogel layer containing at least one polymer and one non-toxic

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photoinitiator compound is present and the hydrogel layer is irradiated with electromagnetic radiation so that the hydrogel is immobilized on the surface of the polymer substrate.

Swan discloses a method comprising forming a polymer layer on a support surface by the use of a coating agent and polymerizable compounds (abstract). Swan provides a method for using a coating agent to form a polymer layer on a support surface. The coating agent provides a first photoreactive group used to attach the coating agent to the substrate and a second photoreactive group used to initiate polymerization of the polymerizable groups on the support surface upon being contacted with electromagnetic radiation (0011-0020). The polymerizable groups taught by Swan include polyvinylpyrrolidinone and polyethylene glycol, which are admitted known hydrogel polymers in the Applicant's specification (0072, 0079). Also, Swan teaches a variety of support surfaces including polypropylene, polyvinyl chloride, polycarbonate, polyolefins and polyurethanes (0085). The support surface materials can be used to fabricate implant devices such as grafts, stents, catheters, dialysis tubing and many other biomedical devices (0087). Swan teaches that the photoinitiator species particularly preferred are thioxanthone, and its derivatives, having excitation energies greater than about 360 nm (0049). Swan teaches irradiating the photoinitiator species with electromagnetic radiation in the 330-340 nm wavelength range (0139).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject

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matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Swan in view of obviousness.

Swan teaches irradiating the photoinitiator species with electromagnetic radiation in the 330-340 nm wavelength range (0139). It would have been obvious to a person ordinarily skilled in the art at the time of the invention to include the radiation range from 170 to 600 nm because it would be advantageous to optimize the wavelength parameters to produce the best product.

Claims 9 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swan in view of Kondo et al (JP 54060386A)

Claims 9 and 17 are drawn to nicotinic acid amide as the initiator compound used in the forming of a polymer hydrogel layer.

Swan discloses a method comprising forming a polymer layer on a support surface by the use of a coating agent and polymerizable compounds (abstract). Swan provides a method for using a coating agent to form a polymer layer on a support surface. The coating agent provides a

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first photoreactive group used to attach the coating agent to the substrate and a second photoreactive group used to initiate polymerization of the polymerizable groups on the support surface upon being contacted with electromagnetic radiation (0011-0020). Swan does not teach nicotinic acid amide as the initiator compound. Kondo teaches the use of nicotinamide derivatives as an initiator for photopolymerizable compounds (abstract). Also, Kondo teaches that the polymerisable compound has an ethylenically unsaturated double bond (abstract). Oligomers having at least one hydroxyl group within the molecule are specifically mentioned as preferred embodiments (abstract). It would have been obvious to a person ordinarily skilled in the art at the time of the invention to combine the use of a nicotinamide initiator with the teaching of Swan because polyethylene glycol is an oligomer that contains hydroxyl groups in the molecule.

### ***Conclusion***

Claims 1-7, 9, 15 and 17 are rejected.

Claims 8, 10-14, 16, 18 and 19 are non-elected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan Schiro whose telephone number is 571-270-5345. The examiner can normally be reached on Monday-Thursday from 8 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on 571-272-0579. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ryan Schiro  
June 24, 2008  
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/Vickie Kim/

Supervisory Patent Examiner, Art Unit 4172